UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,371	03/04/2002	Peng Wang	25885-704	7248

21971 7590 10/21/2003

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 943041050

EXAMINER	
PATTEN, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,371	WANG ET AL.	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-19 are pending in the application.

Election/Restrictions

Claims 20-64 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 8/15/2003. Claims 20-64 were subsequently cancelled in the response filed 8/15/2003.

Claims 1-19 were examined on the merits.

Specification

The disclosure is objected to because of the following reason:

The disclosure does not contain a Brief Description of the Drawings as required by 37 CFR 1.74. Applicant is asked to submit a Brief Description of the Drawings into the Specification without the addition of new matter.

Appropriate correction is required.

Claim Objections

Claims 10, 13 and 15 are objected to because of the following informalities: Claim 1 states 'extract of a plant' which should read 'an extract of a plant'.

Claim 10 states 'and extract of a plant..' which should read 'an extract of a plant'.

Claim 13 states 'formulated in hard or soft-gel..'. It appears that this should read 'into hard or soft-gel'.

Claim 15 states 'is an pharmaceutically' which should properly read 'is a pharmaceutically'.

These are considered minor grammatical/typographical errors.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-19 either recite the term, or dependant upon a claim which recites the term 'Prunella Linn'. This plant is deemed indefinite because it is not found in the art, and Applicant has not described this plant in such a way in order to assure that the ordinary artisan would know if they were in possession of this plant, therefore making the plant name arbitrary and indefinite. Applicant is asked to submit evidence that this particular plant is documented in the literature in order to overcome this rejection.

Claims 3, 10, 17 and 18 all recite 'at least X% by weight' where X is a percentage value. The metes and bounds of 'by weight' is not clearly delineated because it cannot be ascertained weather Applicant intends for this to mean by weight of the extract, or by weight of the composition. Clarification is necessary.

Claims 7 and 19 recite 'ursolic acid, 2α'. It is unclear what '2α' is referring to. There is no clear definition for this term and therefore, it is not understood what Applicants mean by '2α'. Correction is necessary.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because as the state of the art stands, viable treatments for diabetes are rare and the art of phytochemistry is unpredictable with regard to plant extracts.

In the Instant case, Applicants have claimed a composition comprising an extract of *Prunella Linn*. The Instant specification also teaches that the extract is obtained from *Prunella Linn*. The means by which Applicant has phrased this plant by italics, leads the Examiner to believe that 'Prunella' is the genus, which is a known genus of plant, and 'Linn' is the species of plant. However, the Examiner cannot find any evidence of such a plant in terms of this genus/species. According to the state of the art, the term 'Linn.' is commonly documented after the genus/species name as a complimentary reference to the discoverer of the plant ; i.e., 'Linn.' for 'Linnaeus'.

If this is a new species of plant, Applicants have not provided critical information with regard to how to locate this plant, how to identify the plant (characteristics which are unique to this particular species) or even where to purchase this plant material. The skilled artisan would therefore have no indication of how to obtain such a plant which is crucial to making the claimed invention. Accordingly, the skilled artisan would necessarily need to perform undue experimentation in order to practice the claimed invention arising from the lack of guidance present in the Specification with regard to

'*Prunella Linn*'. This experimentation would be *a priori* undue, especially considering that the skilled artisan would not expect to find this particular plant species considering the lack of guidance presented in the Instant specification.

As indicated under the rejection under 35 USC 112 Second paragraph, this rejection can be overcome by evidence which clearly indicates that Prunella *Linn.* was known and documented in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703) 308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

10/15/03

PATRICIA PATTEN
PATENT EXAMINER